

510 (k) Summary

K083250

Submitter's Identification:

AA NeuroMed Company
1911 Rodger Avenue
Port Coquitlam, BC V3C 1M9
Canada

AUG 18 2009

Telephone: 604-941-0551
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Contact person: Hermann Dolker

Date prepared: 10/27/2008

Device identification:

Trade name: NeuroMed Electroanalgesic Delivery Systems
Common name: Interferential Current Therapy
Classification name: Interferential Current Therapy Device,
Product Code: LIH (Unclassified), IPF, GZJ

Predicate Devices Information:

TRANSCUTANEOUS ELECTRICAL NERVE STIMULATOR (Nemectron EDiT) (K932897),

Metron Vectorsurge 5 (K03048)

Device Description:

NeuroMed Electroanalgesic Delivery Systems consist of a system console with a control and display panel, control electronics and software and device accessories including a suction cup electrode applicator, electrodes and cables. The device uses regular household current as a power source. The physical measurements of the device are 17.5" long x 11.5" wide x 5.5" high at a weight of approximately 9 lbs.

NeuroMed Electroanalgesic Delivery Systems is an electrical signal generator which applies sinusoidal current through two pairs of contact electrodes using temporal interference patterns to stimulate muscles and peripheral nerves transcutaneously for the purpose of providing pain relief or as an adjunctive treatment in physical therapy. Alternatively, this device can perform the aforementioned functions by applying sinusoidal current through only one pair of electrodes.

Intended Use:

The intended use of the NeuroMed Electroanalgesic Delivery Systems is the same as for the predicate devices namely to:

Stimulate peripheral nerves for the purpose of providing pain relief
Stimulate motor nerves for the purpose of muscle rehabilitation
Management and symptomatic relief of chronic (long-term) intractable pain.
Adjunctive treatment of post-traumatic pain syndromes
Adjunctive treatment in the management of post-surgical pain problems
Increasing local blood circulation

Maintaining or increasing range of motion

Muscle Re-education

Relaxation of muscle spasms

Prevention or retardation of disuse atrophy

Immediate post-surgical stimulation of the calf muscles to prevent phlebothrombosis

Summary of technological characteristic in comparison to predicate devices:

The NeuroMed Electroanalgesic Delivery Systems and the predicate devices are console type electrical signal generators which apply sinusoidal current through two pairs of contact electrodes to the patient. Their output currents consist of similar intensity and frequency range. They have electronic control circuits with embedded software and use common household current as a power source. They are in compliance with equivalent IEC standards.

Conclusions:

The NeuroMed Electroanalgesic Delivery Systems have the same intended use and similar characteristics as the predicate devices. Documentation supplied in this submission demonstrates that any differences in their technological characteristics do not raise any new concerns of safety or effectiveness. Thus, the NeuroMed Electroanalgesic Delivery Systems can be determined to be substantially equivalent to the the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

AA NeuroMed Corp.
c/o Hermann Dolker
1911 Rodger Avenue
Port Coquitlam, British Columbia
Canada
V3C 1B8

AUG 18 2009

Re: K083250

Trade/Device Name: NeuroMed Electroanalgesic Delivery System

Regulation Number: 21 CFR 882.5890

Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief

Regulatory Class: Class II

Product Code: GZJ, LIH, IPF

Dated: July 27, 2009

Received: August 13, 2009

Dear Mr. Dolker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

Page 2 – Mr. Hermann Dolker

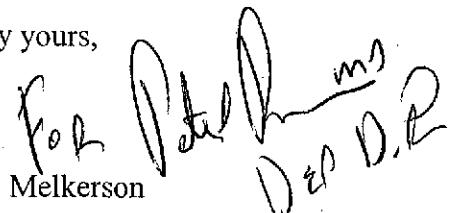
CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K083250**

Device Name: **NeuroMed Electroanalgesic Delivery System**

Indications For Use:

Pain Management for use with interferential and/or TENS mode programs/parameters

Stimulate peripheral nerves for the purpose of providing pain relief.
Management and symptomatic relief of chronic (long-term) intractable pain.
Adjunctive treatment of post-traumatic pain.
Adjunctive treatment in the management of post-surgical pain.

Muscle Stimulation for use with muscle stimulation programs

Increasing local blood circulation.
Maintaining or increasing range of motion.
Muscle Re-education.
Relaxation of muscle spasms.
Prevention or retardation of disuse atrophy.
Immediate post-surgical stimulation of the calf muscles to prevent venous thrombosis.

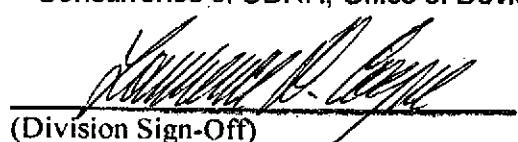
Prescription Use **X**
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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